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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,974	08/09/2000	Thomas Teufel	381-86	5643

7590

12/18/2001

Deborah A. Somerville
KENYON & KENYON
One Broadway
New York, NY 10004

EXAMINER

HUNT, JENNIFER ELIZABETH

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/635,974

Applicant(s)

TEUFEL, THOMAS

Examiner

Jennifer E Hunt

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method of treating a mammal using an EGFR antagonist, classified in class 424, subclass 138.1, and 277.1.
- II. Claims 8-21, drawn to a method of treating a mammal using an EGFR antagonist and phototherapy, classified in class 514, subclass 1, and class 424, subclass 138.1, and 277.1.
- III. Claims 22-38, drawn to a method of treating a mammal using an antagonist and chemotherapy, classified in class 514, subclass 1, and class 424, subclass 138.1, and 277.1.
- IV. Claims 39-43, drawn to a method of treating a mammal comprising administering an EGFR antagonist and phototherapy and chemotherapy, classified in class 514, subclass 1, and class 424, subclass 138.1, and 277.1.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-IV are distinct because they have different method steps, involve administration of different agents, and would produce different treatment efficacies. Further, combination therapies would produce different treatment outcomes, as combinations of therapies can yield variant results, ranging from decreased efficacy to synergistic effect.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If any of Groups I-IV is elected, applicant must further elect from the following distinct categories of species:

A. Members of the EGFR family, for example, EGFR/HER1, or HER2, or HER3, or HER4. These proteins are distinct, having different physiological functions, different mechanisms of action, and play distinct roles in different pathological states.

B. Members of ligands, for example, those listed at page4, lines 9-13. These ligands are distinct, having different physiological functions, different mechanisms of action, and play distinct roles in different pathological states.

C. Types of antagonist:

C1 - Where the antagonist is an antibody

C2 - Where the antagonist is a defective receptor

C3 - Where the antagonist is a small molecule

These proteins are distinct, having different physiological functions, different mechanisms of action, and present unique treatment effects.

D. Types of hyperproliferative disorders, for example, those listed at page 4, lines 14-23. These are completely different disorders which have different causes, produce different symptoms, and require different treatments.

If Group II or IV is elected, applicant must further elect a species of phototherapy, for example, from those listed at page 16, lines 1-8. These therapies are distinct and produce distinct effects.

If Group III or IV is elected, applicant must further elect a species of chemotherapy, for example, those listed at page 14, line 11-page 15, line 31. These chemotherapeutic agents have distinct administration protocols, distinct chemical structures, and different treatment efficacy.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached on Monday-Friday, 6-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Jennifer E Hunt
Examiner
Art Unit 1642

jeh
December 3, 2001


ANTHONY C. CAPUTA
SENIOR PATENT EXAMINER
TECHNOLOGY CENTER 1600